Applicant(s): P. Bonutti Application No.: 10/685,117

Examiner: K. Truong

Remarks

Claims 4, 8-14, 16, 18, and 20-24, 26-29, and 31-38 are pending in this application.

Claim 8 has been amended to correct a typographical error. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §102(e) Rejection

Claims 4, 8-15, 16, 18, 20-24, 26-29, and 31-38 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,919,194 to Anderson ("Anderson'). In response, Applicant respectfully submits that this rejection should be withdrawn.

Anderson relates to an orthopaedic implant, namely a locking device for anchoring to cortical bone for the fixation of fractures of bone and/or dislocations of joints. (Abstract) The locking device includes a cable, a locking member slidable over the cable, and a spreader member attached to a distal end of the cable. (Id).

With reference to Fig. 3 of Anderson, the locking member 40 includes a cylindrical sleeve 42 having a plurality of flanges or fins 44 extending radially therefrom. (Col. 4, lns. 49-53). More preferably, the locking member 40 has four fins 44 integrally formed thereon having a proximal surface 50, and together defining a substantially annular shape. (Id). The fins 44 are separated by notches or gaps 46 therebetween, which extend proximally along a portion of the sleeve 42 and extend radially through to the passage 48 (FIG. 3), thereby allowing the fins 44 to be expanded radially. (Id).

Cambridge Dictionaries Online defines a plate as "a flat piece of something that is hard and does not bend". Locking member 43, being a cylindrical sleeve having a plurality of fins does not therefore form a plate. Moreover, the fins are notched to expand radially, and thus bend.

With further reference to Fig. 3 of Anderson, the capturing sleeve 62 also has a raised portion 68 extending radially from an outer surface 65 of the cylindrical portion 64. (Col. 5, lns. 22-24). Preferably, the raised portion 68 is an annular shaped flange integrally formed around the

Applicant(s): P. Bonutti Application No.: 10/685,117 Examiner: K. Truong

cylindrical portion 64, and including a distal or abutting surface 70. (Id).

Thus, the capturing sleeve 62 likewise does not fit the definition of a plate, particularly as the bone is engaged by an annular shaped flange.

As stated in Anderson, the locking device includes an elongate member, preferably a cable or metal rod... (Col. 2, lns. 28-30). In an alternative embodiment, an elongate substantially rigid rod (not shown) may be provided instead of the cable, the rod having threads extending at least partially along a proximal portion thereof. (Col. 6, lns. 63-66). While maintaining a predetermined tension on the proximal end 24 of the cable 20, the threaded member 80 is rotated, directing it distally into the aperture 74, thereby forcing the flange 78 radially inward and deformationally and/or frictionally engaging the cable 20. (Col. 6, lns. 40-44).

Applicant submits that the cable 20 or rod of Anderson is not a suture as disclosed in the present invention. More particularly, the device disclosed in Anderson would not function as disclosed with a suture, there being the requirement of deformationally and/or frictionally engaging the cable as described.

With reference to Fig. 6 of Anderson, an expanding tool 110 may be provided to expand the fins 44 of the locking member 40 from their contracted condition to their enlarged condition. (Col. 9, lns. 1-4) The tool 110 comprises an elongate tubular member 112, a handle 114, and a tensioning device 116. (Id). The tubular member 112 preferably has a passage 118 extending therethrough for receiving the cable 20... (Id). The proximal end 122 of the tubular member 112 is integrally formed on or attached to the handle 114... (Col. 9, lns. 12-13).

Thus, the tubular member in Anderson does not remain in the bone.

In contrast, in the present Invention, with reference to the figures, the bone suture assembly 32 (FIG. 2) includes a flexible suture 38 which extends across the fracture 26. (¶[0031]). The suture 38 is disposed in a straight cylindrical passage 40 which extends diametrically across a generally cylindrical portion of the bone 20. (Id). The suture 38 extends between a first suture anchor 50 disposed on one side of the fracture 26 and a second suture anchor 52 disposed on the opposite side of the fracture. (¶[0032]). ...a tubular cylindrical member is inserted into the passage 40 and extends diametrically through the bone 20. (¶[0044]). The cylindrical tubular member which is inserted into the passage 40 through the bone 20 performs

Applicant(s): P. Bonutti Application No.: 10/685,117 Examiner: K. Truong

the dual functions of lining the inside of the passage 40 and maintaining the two sections 22 and 24 of the bone in alignment. (¶[0054]). It is contemplated that the cylindrical tubular member could be left in the passage 40 after the bone suture assembly 32 has been installed. (Id).

In the embodiment of the invention illustrated in FIG. 10, a pair of bone plates and rigid fasteners are used in association with a bone suture assembly. (¶[0127]). In the illustrated embodiment of the invention, the plate members 184 and 186 are rigid and are shaped to engage the bone 20g. (¶[0129]). A first suture anchor 50g is pressed against the plate member 184 by tension in a suture 38g. The suture 38g extends through a passage 40g in the bone 20g. A second anchor 52g is pressed against the plate member 186 by the tension in the suture 38g. (¶[0130]). A pair of screws 190 and 192 extend diametrically through the bone 20g between the plate members 184 and 186. (¶[0131]). It is contemplated that shorter screws could be utilized if desired. (¶[0133]). These shorter screws would have relatively coarse bone engaging thread convolutions to hold the short screws and plate members 184 and 186 in place. (Id).

Claim 4 recites, *inter alia*, a bone suture assembly for treating a fracture of a bone comprising: a first rigid bone plate positionable proximate to the bone; a second rigid bone plate positionable proximate to the bone generally opposite the first bone plate; a suture connected with the first and second rigid bone plates to thereby stabilize the fracture, the suture positionable through a passage in the bone; and at least one fastener positionable through the first rigid bone plate into the bone to hold the first rigid bone plate to the bone.

Thus, as described above, Anderson fails to disclose a rigid bone plate, or a suture. In addition, Anderson fails to disclose at least one fastener positionable through the first rigid bone plate into the bone. Specifically, the fastener of Anderson does not pass *into the bone*, as is disclosed in the present invention.

Claim 8 recites, *inter alia*, a bone suture assembly for treating a fracture of a bone comprising: a first bone plate positionable proximate to the bone; a suture positionable through the first bone plate and across the fracture of the bone to thereby stabilize the fracture; and a tubular member positionable in the bone through the fractured, generally orthogonal to the first bone plate, wherein the tubular member remains in the bone such that the suture is disposed within the tubular member.

Applicant(s): P. Bonutti Application No.: 10/685,117 Examiner: K. Truong

As described above, with respect to claim 4, Anderson does not disclose a bone plate or a suture. Anderson further does not disclose a tubular member positionable in the bone, wherein the tubular member remains in the bone.

Claim 13 recites, *inter alia*, A bone suture assembly for treating a fracture of a bone comprising: a first suture anchor positionable proximate to the bone; a rigid bone plate positionable between the first suture anchor and the bone, the rigid bone plate and first suture anchor positionable generally on the same side of the bone; a suture extending through the rigid bone plate and connected with the first suture anchor, the suture positionable across the bone to thereby stabilize the fracture; and at least one fastener positionable through the rigid bone plate into the bone to hold the rigid bone plate to the bone.

As described above, Anderson does not disclose a bone plate or a suture. Moreover, Anderson does not disclose separate elements defining a suture anchor and a bone plate. Additionally, Anderson does not disclose a fastener fastened *into the bone*.

Claim 23 recites, *inter alia*, a method for treating a fracture of a bone comprising: forming at least one passage through the bone, where the passage traverses the fracture; positioning at least one suture anchor proximate to the bone; positioning at least one bone plate between at least one suture anchor and the bone; fastening the at least one bone plate to the bone with at least one screw; moving at least one suture through the passage in the bone and through at least one bone plate; attaching at least one suture to at least one suture anchor; and tensioning at least one suture to stabilize the fracture of the bone.

As described above, Anderson does not disclose a bone plate, suture, or separate suture anchor and bone plates, and further does not disclose fastening a bone plate to the bone with a screw.

Accordingly, claims 4, 8, 13, and 23 are respectfully submitted to be patentable over Anderson. As claims 9-10 depend from claim 8; claims 11-12 and 36-38 depend from claim 4; claims 14, 16, 18, 20-22, and 34-35 depend from claim 13; and claims 24, 26-29, and 31-33 depend from claim 23, and as each recited dependent claim necessarily includes all the elements of its respective base claim, Applicant respectfully submits that these dependent claims are also patentable over Anderson at least for the same reasons. Claim 15 had been cancelled.

Applicant(s): P. Bonutti Application No.: 10/685,117

Examiner: K. Truong

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 102 rejection.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due. However, please charge any required fees (or credit any overpayment of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-009-3).

Respectfully submitted,

Paul D. Bianco, Reg. # 43,500

Customer Number: 33771

FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO

21355 East Dixie Highway, Suite 115

Miami, Florida 33180

Tel: 305-830-2600; Fax: 305-830-2605